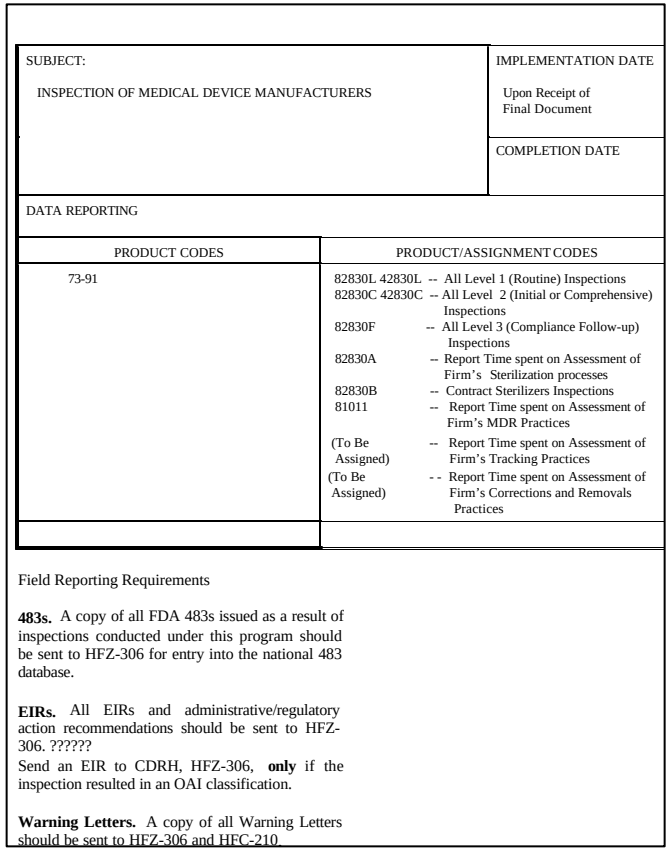
Compliance Program & Warning Letter Pilot

QSIT Workshops

Compliance Program

- Incorporates Several Program areas
- Utilizes QSIT
- Uses Three Levels of Inspection
- Establishes OAI



SUBJECT: INSPECTION OF MEDICAL DEVICE MANUFACTURERS	IMPLEMENTATION DATE: Upon Receipt of Final Document
	COMPLETION DATE

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
73-91	82830L 42830L -- All Level 1 (Routine) Inspections 82830C 42830C -- All Level 2 (Initial or Comprehensive) Inspections 82830F -- All Level 3 (Compliance Follow-up) Inspections 82830A -- Report Time spent on Assessment of Firm's Sterilization processes 82830B -- Contract Sterilizers Inspections 81011 -- Report Time spent on Assessment of Firm's MDR Practices (To Be Assigned) -- Report Time spent on Assessment of Firm's Tracking Practices (To Be Assigned) - - Report Time spent on Assessment of Firm's Corrections and Removals Practices

Field Reporting Requirements

483s. A copy of all FDA 483s issued as a result of inspections conducted under this program should be sent to HFZ-306 for entry into the national 483 database.

EIRs. All EIRs and administrative/regulatory action recommendations should be sent to HFZ-306. ??????
Send an EIR to CDRH, HFZ-306, **only** if the inspection resulted in an OAI classification.

Warning Letters. A copy of all Warning Letters should be sent to HFZ-306 and HFC-210

Comments to Compliance Program

- **WWW.FDA.GOV/CDRH/COMP/7382.845.HTML**
- November 10, 1999
- Dockets Management Branch

CP 7382.845
QS Situation I

- One or more major nonconformities with QS Regulation
  - Total failure to define, document or implement a quality system or one of the seven subsystems
  - A major deficiency in one or more elements of the subsystems
    - QSIT Guide provides guidance
    - Chart A provides seven specific examples, one from each subsystem

more...

CP7382.845 - QS/GMP Situation I

- Products which clearly do not comply with the manufacturer's specifications and/or the QS Regulation and which were not adequately addressed by the CAPA subsystem
- Noncorrection of major deficiencies from previous inspections
- Excessive number of minor nonconformities

CHART A

The examples below are for illustrative purposes only. There are many other possible examples.

Management Controls Subsystem

- 820.20(c)
  Management with executive responsibility did not conduct management reviews at defined intervals and with sufficient frequency to evaluate the suitability and effectiveness of the quality system.

Design Controls Subsystem

- 820.30(g)
  Design validation did not ensure that devices conform to defined user/patient needs and intended uses.

Production and Process Controls Subsystem

- 820.70(a)(2)
  Process parameters and component and device characteristics are not monitored and controlled during production.

Corrective and Preventive Actions Subsystem

- 820.100(a)(1)
  Not all sources of quality data are analyzed to identify existing and potential causes of nonconforming product and other quality problems.

CP7382.845 - QS/GMP Situation II

- Deviations which have a low probability of leading to nonconforming and/or defective devices
- Form FDA 483, Inspectional Observations, serves to inform the establishment of any objectionable findings

Warning Letter Pilot
Quality System Inspections

- http://www.fda.gov/ohrms/dockets/98fr/030899f.txt
- Initiation date March 29, 1999
- Termination date September 8, 2000

Warning Letter Pilot Quality System Inspections

- Following a domestic device quality system inspection which finds current good manufacturing practice (CGMP) deficiencies (situation 1, compliance program (CP) 7382.830 & part V) that warrant a warning letter, the establishment is to be given 15 working days to respond from the issuance date of the list of inspectional observations (FDA483).

Warning Letter Pilot
Quality System Inspections

- If the firm's written response to the FDA483 is deemed be satisfactory by the district office, then a warning letter should not be issued.

Postinspectional Notification Letter

- When no warning letter is issued by the district office due to the firm's satisfactory written response, the postinspectional notification letter should be sent to the establishment.

Warning Letter Pilot Does Not Apply to:

- Non quality system inspections such as mammography, radiological health, and bioresearch inspections;
- Establishments that manufacture devices as well as other FDA regulated products;
- Establishments that manufacture devices that are regulated by the Center for Biologics Evaluation and Research (CBER);

Warning Letter Pilot Does Not Apply to:

- Recidivous establishments as defined in CP 7382.830;
- Any inspection that uncovers CGMP, premarket notification submission (510(k)), or labeling deficiencies that may cause serious adverse health consequences;

Warning Letter Pilot Does Not Apply to:

- A compliance followup inspection when the previous inspection resulted in a warning letter or regulatory action for quality system, 510(k), or labeling violations;
- Any inspection that discloses other significant device violations (e.g. medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action; or...

Warning Letter Pilot Does Not Apply to:

- A situation where the firm's management failed to make promptly available to FDA personnel all requested information and records required by regulations or laws enforced by FDA.

Thank You